
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): April 1, 2024

Akari Therapeutics, Plc

(Exact Name of Registrant as Specified in Charter)

England and Wales

(State or other jurisdiction
of incorporation)

001-36288

(Commission File Number)

98-1034922

(I.R.S. Employer
Identification No.)

**22 Boston Wharf Road FL 7
Boston, MA 02210**

(Address, including zip code, of Principal Executive Offices)

Registrant's telephone number, including area code: (929) 274-7510

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class: | Trading Symbol(s) | Name of each exchange on which registered |
|--|-------------------|--|
| American Depositary Shares, each representing 2,000 Ordinary Shares | AKTX | The Nasdaq Capital Market |
| Ordinary Shares, par value \$0.0001 per share* | | |

*Trading, but only in connection with the American Depositary Shares.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On April 1, 2024, Akari Therapeutics, Plc. (the “Company”) issued a press release announcing its financial results for the second half and full year ended December 31, 2023 and certain other information. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information furnished pursuant to this Item 2.02 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company’s filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing. Except as required by law, the Company undertakes no duty or obligation to publicly update or revise the information so furnished.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press Release, dated April 1, 2024, of Akari Therapeutics, Plc. |
| 104 | The cover page from this Current Report on Form 8-K, formatted in Inline XBRL. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Akari Therapeutics, Plc

Date: April 1, 2024

By: /s/ Rachele Jacques

Rachele Jacques
President and Chief Executive Officer

Akari Therapeutics Reports Full-Year 2023 Financial Results and Recent Highlights

BOSTON and LONDON, April 1, 2024 (GLOBE NEWSWIRE) – Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company developing advanced therapies for autoimmune and inflammatory diseases, has reported financial results for the full year 2023 as well as recent company highlights.

“Amidst challenging economic conditions during 2023 in the biotech sector and beyond, the Akari team advanced our Phase 3 and pre-clinical development programs and paved the way for a merger that, upon closing, will expand our pipeline and open the door to new potential growth and value creation opportunities,” said Rachelle Jacques, Akari President and CEO. “We believe we are building strong momentum and we’re excited about the possibilities that exist for our combined company.”

Company Highlights

Akari announced the company has reached a definitive agreement with Peak Bio Inc. (Peak Bio) to merge as equals in an all-stock transaction. The combined entity will operate as Akari Therapeutics, Plc, which is expected to continue to be listed and trade on the Nasdaq Capital Market as AKTX.

Following closing, the company will have an expanded pipeline that contains multiple compelling assets spanning early and late development stages, including: a robust antibody drug conjugate (ADC) toolkit with novel payload and linker technologies, a Phase 2-ready neutrophil elastase inhibitor (NEI) program targeting alpha-1 antitrypsin deficiency (AATD), nomacopan, a bispecific inhibitor of two immune pathways (complement C5 and leukotriene B4/LTB4) in Phase 3 development for pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA), and long-acting PAS-nomacopan for geographic atrophy (GA).

A strategic assessment of the pipeline is planned to evaluate development of the four programs including program prioritization, updated timelines, near-term value creation

opportunities, and other considerations. The assessment is expected to be complete prior to the closing of the merger.

The Phase 3 Part A clinical trial of investigational nomacopan in pediatric HSCT-TMA is studying multiple age groups with a focus on PK/PD and dose confirmation. Akari is continuing to recruit patients into the Part A portion of the Phase 3 clinical trial that has treated 10 patients to date. Enrollment in Part A is guided by new consensus criteria published in 2023 supporting earlier screening and diagnosis of high-risk (severe) patients with HSCT-TMA. The Phase 3 clinical trial also is expected to include a Part B portion focusing on safety and efficacy. Plans for initiation of the Part B study will be guided by the strategic pipeline assessment.

HSCT-TMA is a rare complication of stem cell transplant that has no approved treatment options and an 80% mortality rate among severe patients. Nomacopan is in development as potentially the first treatment approved for the condition.

Akari was granted orphan drug designation from the European Commission for treatment in hematopoietic stem cell transplantation, and FDA Orphan Drug, Fast Track and Rare Pediatric Disease designations for nomacopan for the treatment of pediatric HSCT-TMA. With the FDA Rare Pediatric Disease Designation, Akari is eligible to receive a Priority Review Voucher (PRV) upon approval of nomacopan that it can either redeem for priority review of a subsequent marketing application for a different product or sell to a third party.

During 2023, Akari also advanced the long-acting version of nomacopan (PASylated nomacopan) into the final stages of pre-clinical development as a treatment for geographic atrophy (GA). PAS-nomacopan is being developed with the potential to address significant unmet patient needs, including a longer dose interval between intravitreal injections and reduction of choroidal neovascularization (CNV) risk associated with approved complement-only inhibitors currently used for treatment of GA. Positive pre-clinical results, including an advanced high-yielding manufacturing process that provides a drug with specifications considered suitable for intravitreal administration, support the potential initiation of clinical development with Phase 1 single and multiple ascending dose (SAD/MAD) testing to evaluate safety and pharmacokinetics/ pharmacodynamics (PK/PD). A progressive and

sight-threatening condition, GA is estimated to affect 5 million people worldwide, including 1 million patients in the U.S.

Full-Year 2023 Financial Results

As of December 31, 2023, the company had cash of approximately \$3.8 million. In March 2024, the company received approximately \$2.0 million in gross proceeds from certain existing investors from the sale of ADSs in a private placement and is planning to secure additional capital in the second quarter of 2024.

Research and development expenses were approximately \$5.5 million for the year ended December 31, 2023, as compared to approximately \$9.6 million for the same period in 2022.

General and administrative expenses were approximately \$11.4 million for the year ended December 31, 2023, as compared to approximately \$13.5 million for the same period in 2022.

Total other income, net was approximately \$6.8 million for the year ended December 31, 2023, as compared to approximately \$5.3 million for the same period in 2022, of which \$6.6 million and \$5.0 million (net) was the result of net non-cash gains related to the company's liability-classified warrants issued in connection with the company's September 2022 private placement transaction.

Net loss was approximately \$10.0 million for the year ended December 31, 2023, as compared to net loss of approximately \$17.7 million for the same period in 2022. Excluding the net non-cash gains of approximately \$6.6 million and \$5.0 million (net) for the years ended December 31, 2023 and 2022, respectively, related to the company's liability-classified warrants, net loss was \$16.6 million and \$22.7 million, respectively.

About Akari Therapeutics

Akari Therapeutics, plc (Nasdaq: AKTX) is a biotechnology company developing advanced therapies for autoimmune and inflammatory diseases. Akari's lead asset, investigational nomacopan, is a bispecific recombinant inhibitor of complement C5 activation and leukotriene

B4 (LTB4) activity. Akari's pipeline includes a Phase 3 clinical trial program investigating nomacopan for pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA).

Akari has been granted Orphan Drug, Fast Track and Rare Pediatric Disease designations from the FDA for nomacopan for the treatment of pediatric HSCT-TMA and orphan drug designation from the European Commission for treatment in hematopoietic stem cell transplantation. Akari's pipeline also includes pre-clinical research of long-acting PAS-nomacopan in geographic atrophy (GA).

For more information about Akari, please visit akaritx.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding: Akari's clinical development plans, the anticipated closing of Akari's merger with Peak Bio, Akari's cash and financial resources and expected cash runway. These statements involve known and unknown risks, uncertainties and other important factors that may cause Akari's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, these statements can be identified by terms such as "may," "might," "will," "should," "expect," "plan," "aim," "seek," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "forecast," "potential" or "continue" or the negative of these terms or other similar expressions.

The forward-looking statements in this press release are only predictions. Akari has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that Akari believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions,

some of which cannot be predicted or quantified and some of which are beyond Akari's control, including, among others: results of Akari's clinical development activities in its drug candidates in development on the timelines anticipated; Akari's ability to successfully integrate operations with Peak Bio; the accuracy of Akari's estimates regarding its capital requirements; and Akari's ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are described more fully in the "Risk Factors" section of Akari's most recent filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in these forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, Akari operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that Akari may face. Except as required by applicable law, Akari does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

For more information

Investor Contact:

Mike Moyer

LifeSci Advisors

(617) 308-4306

mmoyer@lifesciadvisors.com

Media Contact:

Eliza Schleifstein

Schleifstein PR

(917) 763-8106

eliza@schleifsteinpr.com

Akari Therapeutics Plc
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited, in U.S. dollars)

| <i>(in thousands, except per share amounts)</i> | Year Ended December 31, | |
|---|----------------------------|--------------------|
| | 2023 | 2022 |
| Operating expenses: | | |
| Research and development | \$ 5,450 | \$ 9,561 |
| General and administrative | 11,356 | 13,527 |
| Loss from operations | (16,806) | (23,088) |
| Other income (expense): | | |
| Excess in fair value of warrant liability over cash proceeds | — | (1,963) |
| Change in fair value of warrant liability | 6,599 | 6,946 |
| Other income, net | 199 | 357 |
| Net loss | <u>\$ (10,008)</u> | <u>\$ (17,748)</u> |
| Net loss per ordinary share — basic and diluted | <u>\$ (0.00)</u> | <u>\$ (0.00)</u> |
| Weighted-average number of ordinary shares used in computing net loss per share — basic and diluted | <u>9,788,980</u> | <u>6,243,462</u> |

Akari Therapeutics Plc
Condensed Consolidated Balance Sheet Data
(Unaudited, in U.S. dollars)

| <i>(\$'s in thousands)</i> | December 31, 2023 | December 31, 2022 |
|---|----------------------|----------------------|
| Cash | \$ 3,845 | \$ 13,250 |
| Other assets | 510 | 582 |
| Total assets | <u>\$ 4,355</u> | <u>\$ 13,832</u> |
| Total liabilities | \$ 4,584 | \$ 12,041 |
| Total shareholders' (deficit) equity | (229) | 1,791 |
| Total liabilities and shareholders' (deficit) equity | <u>\$ 4,355</u> | <u>\$ 13,832</u> |

